

**Reviewer:** Breann Hanson

**Date:** December 14, 2010

**Risk Manager (EPA):** BeWanda Alexander, RM Team 13

**STUDY TYPE:** Acute Dermal Toxicity - Rat; OPPTS 870.1200; OECD 402

**TEST MATERIAL:** Bifenthrin Technical (Bifenthrin: 96%; white powder)

**CITATION:** Liao, X. (2001) Acute Dermal Toxicity Study of Bifenthrin Technical in Rats. Study Number: S010210060; Report Number: 09-PRA-Aceto-044. Unpublished study prepared by Supervision and Test Center for Pesticide Safety Evaluation and Quality Control. May 10, 2001. MRID 47902605.

**SPONSOR:** Jiangsu Yangnong Chemical Co., Ltd.

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 47902605), 5/sex/group young adult rats (age: not reported; weight: 186-223 g males, 186-223 g females; source: Animals Raising Room, China Medical University, China; strain: Wistar) were dermally exposed to Bifenthrin Technical (Bifenthrin: 96%; white powder) at a dose of either 215, 464, 1000 or 2150 mg/kg bw. The test substance was suspended with distilled water and applied directly to the dose site, covered with plastic film and gauze, secured with tape and left in place for only 4 hours. Post-exposure, the dose area was rinsed with warm water. Individual body weights were recorded prior to application (study day 1) and again on study days 3, 7 and 14. The animals were observed for clinical signs of toxicity hourly for the first 6-hours post-dosing and at least twice daily thereafter for the remainder of the 14-day study period. No animals were necropsied.

This acute dermal study is classified Unacceptable. It does not satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat. As noted by the study author (pg. 6) "...[a]fter four hours, the coverings were removed..."; OPPTS 870.1200 Guidelines state that acute dermal toxicity are the "...adverse effects occurring within a short time of dermal application of a single dose of a substance or multiple doses given within a 24-hour period". As the registrant has claimed their proposed product is substantially similar to EPA Reg. No. 83520-5, this reviewer will access dermal acute toxicity based on similarity to 83520-5. Please see conclusions under "Comments and Recommendations".

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.